

Chinese Patent Publication No. 1051471C, published April 19, 2000

Application No. 97116955.1, filed March 10, 2000; Inventor: SU Shen-xing; Assignee: SU Shen-xing

A MEDICINE COMPOSITION FOR CURING OSTEOPOROSIS

[54] [Name of Invention] A Medicine Composition for Curing Osteoporosis

[57] Abstract

This invention is a medicine composition to treat osteoporosis, the composition includes root of American ginseng, cordyceps, prepared rehmannia root, tortoise shell and plastron, root of Chinese angelica, root of common peony, root of red-rooted salvia, Williams elder branchlets, pyrite, meat of mitten crab, oysters, root and rhizome of medicinal rhubarb, roasted nux vomica, peach kernel, and safflower flower; upon preparing, the above-mentioned medicine composition can turn into a conventional medicinal preparation.

SPECIFICATION

1. A medicine composition to treat osteoporosis characterized in that this composition is prepared from the following pharmaceutical feedstock as the active ingredients in the following dosages:

root of American ginseng	20 – 80 parts
cordyceps	10 – 40 parts
prepared rehmannia root	20 – 80 parts
tortoise shell and plastron	30 – 80 parts
root of Chinese angelica	30 – 80 parts
root of common peony	30 – 80 parts
root of red-rooted salvia	30 – 80 parts
Williams elder branchlets	80 – 120 parts
pyrite	80 – 120 parts
meat of mitten crab	80 – 120 parts
oysters	80 – 120 parts
root and rhizome of medicinal rhubarb	30 – 80 parts
roasted nux vomica	30 – 80 parts
peach kernel	30 – 80 parts
safflower flower	10 – 40 parts

2. The above-mentioned medical composition according to Claim 1, characterized in that the above-mentioned weight proportion of individual components is:

root of American ginseng	50 parts
cordyceps	25 parts
prepared rehmannia root	50 parts
tortoise shell and plastron	50 parts
root of Chinese angelica	50 parts
root of common peony	50 parts
root of red-rooted salvia	50 parts
Williams elder branchlets	100 parts
pyrite	100 parts
meat of mitten crab	100 parts
oysters	100 parts

root and rhizome of medicinal rhubarb	50 parts
roasted nux vomica	50 parts
peach kernel	50 parts
safflower flower	15 parts

3. A composition according to claims 1 or 2 characterized in that the said composition also includes excipients.

SPECIFICATION

This invention is a medicine composition to treat osteoporosis. The components of this composition are herbal remedies of the traditional Chinese medicine that are very effective in the treatment and prevention of osteoporosis. This invention also offers a formulation prepared from this composition and falls under the purview of Chinese medicine.

As our quality of life improves and population ages, the size of elderly population continually grows, osteoporosis of retrogressive physiological etiology has become a major health problem of the elderly. Osteoporosis is a disease of the old age and a commonly occurring disease, but we so far domestically, we don't have an especially effective formulation in Chinese traditional medicine. The characteristic features of osteoporosis are the reduction of bone mass, the degradation of bone microstructure leading to increasing bone fragility and readily occurring bone fractures of the lumbar vertebra compression origin, femur and cervical bone fractures, as well as wrist and radial bone fractures. These fractures, and in particular, lumbar vertebra fractures, frequently occur without the impact of any obvious external force and are discovered only by the sudden onset of sharp lumbodorsal pain. As life expectancy increases and so does the elderly population, the hazard of this condition becomes ever greater. Therefore, finding an effective traditional Chinese medication for the prevention and treatment of osteoporosis becomes a major task of modern medicine.

The purpose of this invention is to develop a medicine composition for the treatment of osteoporosis.

Based on the traditional Chinese medicine theory of the "kidneys being in charge of bones," the root cause of the disease is the deficiency of the kidneys in osteoporosis patients; in addition there is also the difference between the Yin deficiency of kidney and Yang deficiency of kidney. Applying the traditional Chinese medicine's principle of differentiated treatment based on pathogenesis obtained through the differentiation of symptoms and signs and in accordance with the national diagnostic criteria with regard to Yin deficiency of kidney and Yang deficiency of kidney, in patients with Yin deficiency of kidney, kidney Yin is supplemented, Qi is promoted and blood nourished, bones are strengthened and muscles relaxed, blood circulation is promoted to dispel blood stasis and stop pain. The inventor summarized numerous cases in his abundant clinical experience and researched and developed medication that is specifically intended to treat Yin deficiency of kidney.

The medicine composition of this invention is made up of the following, in parts by weight:

root of American ginseng	20 – 80 parts
cordyceps	10 – 40 parts
prepared rehmannia root	20 – 80 parts
tortoise shell and plastron	30 – 80 parts
root of Chinese angelica	30 – 80 parts
root of common peony	30 – 80 parts
root of red-rooted salvia	30 – 80 parts
Williams elder branchlets	80 – 120 parts
pyrite	80 – 120 parts
meat of mitten crab	80 – 120 parts
oysters	80 – 120 parts
root and rhizome of medicinal rhubarb	30 – 80 parts
roasted nux vomica	30 – 80 parts
peach kernel	30 – 80 parts
safflower flower	10 – 40 parts

The preferred weight proportion of the above-mentioned medicine composition of this invention is:

root of American ginseng	50 parts
cordyceps	25 parts
prepared rehmannia root	50 parts
tortoise shell and plastron	50 parts
root of Chinese angelica	50 parts
root of common peony	50 parts
root of red-rooted salvia	50 parts
Williams elder branchlets	100 parts
pyrite	100 parts
meat of mitten crab	100 parts
oysters	100 parts
root and rhizome of medicinal rhubarb	50 parts
roasted nux vomica	50 parts
peach kernel	50 parts
safflower flower	15 parts

The medicine composition described in this invention can be prepared according to conventional preparation technology, manufacturing any of the dosage forms suitable for clinical usage, such as pills, tablets, gel tabs, powders, syrup, liquids for oral administration, suspensions, granules, etc.

In the process of manufacturing the above-mentioned medication of this invention, regular pharmaceutical excipients can be added, such as crumbling agents, bonding agents, flavorings, preservatives, fillers, solubilizers, fluxing agents, lubricants, colorings, etc.

The preparation method of the medicine pills of this invention (product name Yonggudan) is as follows:

The root of American ginseng, cordyceps, and meat of mitten crab are quickly freeze-dried and made into powder retaining biological activity; pyrite, oysters, tortoise shell and plastron, root and rhizome of medicinal rhubarb, as well as roasted nux vomica are ground into fine powder, and the rest of the *materia medica* is made into clear cream as specified by the universal preparation principles of pharmacopoeia, then mixed with the above-mentioned medicine powders and blended with honey to make pills. Every pill weighs 6 g.

The effect of this invention is: kidney Yin is supplemented, Qi is promoted and blood nourished, bones are strengthened and muscles relaxed, blood circulation is promoted to dispel blood stasis.

Indication: Yin deficiency of the Kidney osteoporosis.

Clinical applications: osteoporosis, lumbodorsal aching pains, both knees aching and limp, bone fracture pain combined with dizziness and blurred vision, hot flashes and night sweat, dry mouth and throat, red tongue with a little fur, thready and rapid pulse. To be taken one pill at a time, three times a day; to be taken after meals with 25 ml sweetened vinegar to which water is added as needed. The treatment course is 30 days long.

From 1995 to 1997, we treated 30 cases of osteoporosis with the medication of this invention. The X-rays of 30 patients revealed different degrees of bone density loss in thoracic vertebra and hipbones. These included 6 cases of lumbar vertebra compression bone fractures, 4 cases were femoral neck fractures, 1 case of radius fracture, and 1 case of hipbone fracture. All 30 patients had histories of lumbodorsal pains in various degrees, as well as knee joint and hip pain.

The criteria for the evaluation of the curative effect are:

Evidently effective means that after using the medication the pain completely vanished, and motor function markedly improved;

Effective means that after using the medication, the pain was alleviated, and motor functions can improve.

Ineffective means that after using the medication, the pain was not alleviated, and other medications still must be taken.

According to the above criteria for the evaluation of curative effect, the treatment results are as follows:

Curative effect	Number of cases	%	Women		Men	
			Number of cases	%	Number of cases	%
Evidently effective	13	43	10	33.3	3	10
Effective	15	50	10	33.3	5	16.8
Ineffective	2	7	1	3.3	1	3.3

The total curative effect of this medicine composition against osteoporosis is 93%.

Practical Example 1

Root of American ginseng – 50 g; cordyceps 25 g; prepared rehmannia root – 50 g; tortoise shell and plastron 50 g; root of Chinese angelica – 50 g; root of common peony – 50 g; root of red-rooted salvia – 50 g; Williams elder branchlets – 100 g; pyrite – 100 g; meat of mitten crab – 100 g; oysters – 100 g; root and rhizome of medicinal rhubarb – 50 g; roasted nux vomica – 50 g; peach kernel – 50 g; safflower flower – 50 g.

According to the prescription, the root of American ginseng, cordyceps, and meat of mitten crab were quickly freeze-dried and made into powder retaining biological activity; pyrite, oysters, tortoise shell and plastron, root and rhizome of medicinal rhubarb, as well as roasted nux vomica were ground into fine powder, and the rest of the *materia medica* was made into clear cream as specified by the universal preparation principles of pharmacopoeia, then mixed with the above-mentioned medicine powders and blended with honey to make pills. 100 pills were made, and each pill weighed 6 g.

Practical Example 2

Root of American ginseng – 60 g; cordyceps 10 g; prepared rehmannia root – 80 g; tortoise shell and plastron 80 g; root of Chinese angelica – 40 g; root of common peony – 50 g; root of red-rooted salvia – 80 g; Williams elder branchlets – 120 g; pyrite – 90 g; meat of mitten crab – 90 g; oysters – 90 g; root and rhizome of medicinal rhubarb – 40 g; roasted nux vomica – 50 g; peach kernel – 60 g; safflower flower – 25 g.

According to the prescription, the root of American ginseng, cordyceps, and meat of mitten crab were quickly freeze-dried and made into powder retaining biological activity; pyrite, oysters, tortoise shell and plastron, root and rhizome of medicinal rhubarb, as well as roasted nux vomica were ground into fine powder, and the rest of the *materia medica* was made into clear cream as specified by the universal preparation principles of pharmacopoeia, then mixed with the above-mentioned medicine powders and blended with honey to make pills. Each pill weighed 6 g.

Practical Example 3

Root of American ginseng – 80 g; cordyceps 10 g; prepared rehmannia root – 80 g; tortoise shell and plastron 80 g; root of Chinese angelica – 40 g; root of common peony –

50 g; root of red-rooted salvia – 80 g; Williams elder branchlets – 120 g; pyrite – 90 g; meat of mitten crab – 100 g; oysters – 100 g; root and rhizome of medicinal rhubarb – 30 g; roasted nux vomica – 40 g; peach kernel – 30 g; safflower flower – 20 g.

According to the prescription, the root of American ginseng, cordyceps, and meat of mitten crab were quickly freeze-dried and made into powder retaining biological activity; pyrite, oysters, tortoise shell and plastron, root and rhizome of medicinal rhubarb, as well as roasted nux vomica were ground into fine powder, and the rest of the *materia medica* was made into clear cream as specified by the universal preparation principles of pharmacopoeia, then mixed with the above-mentioned medicine powders and blended with honey to make pills. 100 pills were made, and each pill weighed 6 g.

[19]中华人民共和国国家知识产权局

[51]Int. Cl⁷

A61K 35/84

A61K 35/78

A61P 19/10

[12]发明 专利 说明书

[21]专利号 97116955.1

[45]授权公告日 2000年4月19日

[11]授权公告号 CN 1051471C

[22]申请日 1997.9.29 [24]授权日 2000.3.10

[21]申请号 97116955.1

[73]专利权人 苏顺兴

地址 900 台湾省屏东市公裕街 433 号

[72]发明人 苏顺兴

[56]参考文献

实用儿科临床杂志 1990,5(4) 1990. 1. 1 尹钟洙,
龙社壮骨冲剂药理学研究

中医杂志 1992,23(11) 1992. 1. 1 梁立等,补肾中
药治疗骨质疏松症临床观察

中医杂志 1992,23(9) 1992. 1. 1 王林元,新伤膏治
疗腰骨软骨软化症 76 例报告

审查员 唐晓帆

[74]专利代理机构 北京科龙环宇专利事务所

代理人 张 铭

权利要求书 2 页 说明书 4 页 附图页数 0 页

[54]发明名称 一种治疗骨质疏松症的药物组合物

[57]摘要

本发明是一种治疗骨质疏松症的药物组合物,该组
合物的组成包括西洋参、冬虫夏草、熟地、龟板、当归、赤
芍、丹参、接骨木、自然铜、鳖、牡蛎、大黄、炙马钱子、桃
仁、红花;所述的药物组合物可以制备成常规的药物制
剂。

ISSN 1 0 0 8 - 4 2 7 4

99.10.19

权 利 要 求 书

1、一种治疗骨质疏松症的药物组合物，其特征在于该组合物采用下列用量的作为活性成份的原料制成：

西洋参	20-80份
冬虫夏草	10-40份
熟地	20-80份
龟板	30-80份
当归	30-80份
赤芍	30-80份
丹参	30-80份
接骨木	80-120份
自然铜	80-120份
蟹	80-120份
牡蛎	80-120份
大黄	30-80份
炙马钱子	30-80份
桃仁	30-80份
红花	10-40份。

2、根据权利要求1上述的药物组合物，其特征在于所述的各组份的重量比为：

西洋参	50份
冬虫夏草	25份
熟地	50份
龟板	50份
当归	50份
赤芍	50份
丹参	50份
接骨木	100份
自然铜	100份
蟹	100份
牡蛎	100份

99·10·19

大黄 50份

炙马钱子 50份

桃仁 50份

红花 15份。

3、根据权利要求1或2所述的组合物，其特征在于该组合物中还含有赋形剂。

说 明 书

一种治疗骨质疏松症的药物组合物

本发明是一种治疗骨质疏松症的药物组合物，该组合物的组成为我国的传统中草药，对骨质疏松症的治疗和预防具有良好的功效，本发明还提供了以该组合物制备而成的药剂，属于中药领域。

随着现代生活水平的提高，人口寿命逐渐增长，老年人口越来越多，由此带来的退行性生理疾病——原发性骨质疏松症已经成为老年健康的重要疾病之一。骨质疏松症是一种老年病，常见病，目前国内尚无特效的中药制剂。骨质疏松症的特征是骨量低下，骨组织微结构退化导致骨脆性增加，极易造成腰椎压缩性骨折、股骨颈骨折及手腕部、桡骨骨折。这些骨折，尤其是腰椎骨折，往往在没有明显外力作用下发生，常常表现突然腰背剧痛始被发现。随着人口寿命的增长，老年人数的增多，这种病的危害就越来越严重。因此，寻找一种有效预防和治疗骨质疏松症的中药，是当前医学界的重要课题之一。

本发明目的是开发一种治疗骨质疏松症的药物组合物。

根据中医“肾主骨”的理论，骨质疏松症患者肾虚是病之根本。治病必求于本，且肾虚又有肾阴虚、肾阳虚之分。运用中医辩证施治的原则，按照全国关于肾阴虚、肾阳虚诊断标准，对本病肾阴虚者，补肾阴，益气养血，壮骨舒筋，活血祛瘀止痛。发明人在临床实践中通过大量病例总结，研制出了治疗骨质疏松症偏肾阴虚的药物。

本发明药物组合物按重量份计其组成是：

西洋参 20 - 80 份

冬虫夏草 10 - 40 份

熟地 20 - 80 份

龟板 30 - 80 份

当归 30 - 80 份

赤芍 30 - 80 份

丹参 30 - 80 份

接骨木 80 - 120 份

自然铜 80 - 120 份

99.10.19

蟹 80 - 120 份
牡蛎 80 - 120 份
大黄 30 - 80 份
炙马钱子 30 - 80 份
桃仁 30 - 80 份
红花 10 - 40 份

本发明所述的药物组合物其优选重量配比为：

西洋参 50 份
冬虫夏草 25 份
熟地 50 份
龟板 50 份
当归 50 份
赤芍 50 份
丹参 50 份
接骨木 100 份
自然铜 100 份
蟹 100 份
牡蛎 100 份
大黄 50 份
炙马钱子 50 份
桃仁 50 份
红花 15 份

本发明所述的药物组合物，可以按照常规的制剂工艺，制备成任何一种适合于临幊上使用的药物剂型，如，丸剂、片剂、胶囊剂、散剂、糖浆剂、口服液、混悬剂、颗粒剂等。

在制备本发明上述的药物剂型过程中，可以加入常规的药物赋形剂，例如，崩解剂、粘合剂、调味剂、防腐剂、填充剂、增溶剂、助溶剂、润滑剂、色素等。

本发明药物丸剂（商品名为勇骨丹）的制备方法是：

将西洋参、冬虫夏草、蟹速冻干燥，为末，保持生物活性。自然铜、牡蛎、龟板、大黄、炙马钱子研细末，余下诸药按药典制剂通则规定制成清膏，然后与上述药粉混合，炼蜜为丸，每丸重 6 克。

本发明药物的功效是：补肾阴、益气养血、壮骨舒筋、活血化瘀。
主治：肾阴虚型骨质疏松症。

临床应用：骨质疏松、腰背酸痛、丙膝酸软、骨折疼痛兼见头晕眼花、潮热盗汗、咽干口燥、舌红少苔、脉细数者，每次服一丸，每日三次，饭后甜醋 25 毫升兑水适量送服，30 天为一疗程。

自 1995 年至 1997 年，应用本发明药物治疗骨质疏松症病人 30 例，30 例病人骨 X 线平片显示：胸椎、髋骨均有不同程度骨密度降低。其中，6 例腰椎压缩性骨折，4 例股骨颈骨折，1 例桡骨骨折，1 例髋骨骨折。30 例病人均有不同程度腰背疼痛病史，膝关节及髋部疼痛病史。

对治疗结果的疗效评定标准是：

显效为用药后疼痛完全消失，活动功能显著增进；

有效为用药后疼痛减轻，活动功能改善；

无效为用药后疼痛未减轻，仍需服用其他药物。

按上述疗效评价标准，治疗结果如下表：

疗效	例数	%	女		男	
			例数	%	例数	%
显效	13	43	10	33.3	3	10
有效	15	50	10	33.3	5	16.8
无效	2	7	1	3.3	1	3.3

本发明药物组合物治疗骨质疏松症总有效率 93 %。

实施例 1

西洋参 50 克 冬虫夏草 25 克 熟地 50 克 龟板 50 克

当归 50 克 赤芍 50 克 丹参 50 克 接骨木 100 克

自然铜 100 克 蟹 100 克 牡蛎 100 克 大黄 50 克

炙马钱子 50 克 桃仁 50 克 红花 15 克

按照处方量取西洋参、冬虫夏草、蟹速冻干燥，为末，保持生物活性，将自然铜、牡蛎、龟板、大黄、炙马钱子研细末，余下诸药按药典制剂通则规定制成膏膏，然后与上药粉混合，炼蜜为丸，制成 100 丸，每丸重 6 克。

实施例 2

西洋参 60 克 冬虫夏草 30 克 熟地 40 克 龟板 40 克
当归 70 克 赤芍 30 克 丹参 40 克 接骨木 80 克
自然铜 90 克 蟹 90 克 牡蛎 90 克 大黄 40 克
炙马钱子 50 克 桃仁 60 克 红花 25 克

按照处方量取西洋参、冬虫夏草、蟹速冻干燥，为末，保持生物活性。自然铜、牡蛎、龟板、大黄、炙马钱子研细末，余下诸药按药典制剂通则规定制成清膏，然后与上药粉混合，炼蜜为丸，每丸重 6 克。

实施例 3

西洋参 80 克 冬虫夏草 10 克 熟地 80 克 龟板 80 克
当归 40 克 赤芍 50 克 丹参 80 克 接骨木 120 克
自然铜 90 克 蟹 100 克 牡蛎 100 克 大黄 30 克
炙马钱子 40 克 桃仁 30 克 红花 20 克

按照处方量取西洋参、冬虫夏草、蟹速冻干燥，为末，保持生物活性。自然铜、牡蛎、龟板、大黄、炙马钱子研细末，余下诸药按药典制剂通则规定制成清膏，然后与上药粉混合，炼蜜为丸，制成 100 丸，每丸重 6 克。